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10/626,158 07/24/2003 Rucy J. Yu 570 7590 12/13/2005  AKIN GUMP STRAUSS HAUER & FELD L.L.P. ONE COMMERCE SQUARE	8976-224U1	9696
AKIN GUMP STRAUSS HAUER & FELD L.L.P.	·	
	EXAM	IINER
ONE COMMERCE SQUARE	LAMM, MARINA	
2005 MARKET STREET, SUITE 2200	ART UNIT	PAPER NUMBER
PHILADELPHIA, PA 19103	1616	<del>-</del>

DATE MAILED: 12/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)		
Office Action Summary	10/626,158	YU ET AL.		
	Examiner	Art Unit		
	Marina Lamm	1616		
The MAILING DATE of this communicati Period for Reply	on appears on the cover sheet w	ith the correspondence address		
A SHORTENED STATUTORY PERIOD FOR WHICHEVER IS LONGER, FROM THE MAIL!  - Extensions of time may be available under the provisions of 37 after SIX (6) MONTHS from the mailing date of this communice. If NO period for reply is specified above, the maximum statutory.  - Failure to reply within the set or extended period for reply will, E Any reply received by the Office later than three months after the earned patent term adjustment. See 37 CFR 1.704(b).	NG DATE OF THIS COMMUNI CFR 1.136(a). In no event, however, may a tion. period will apply and will expire SIX (6) MOI y statute, cause the application to become A	CATION. reply be timely filed  NTHS from the mailing date of this communication. BANDONED (35 U.S.C. § 133).		
Status				
1) Responsive to communication(s) filed or	1 .			
	This action is non-final.			
B)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is				
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.				
Disposition of Claims				
4)⊠ Claim(s) <u>1-25</u> is/are pending in the application.				
4a) Of the above claim(s) is/are withdrawn from consideration.				
5) Claim(s) is/are allowed.				
6) Claim(s) is/are rejected.				
7) Claim(s) is/are objected to.				
8) Claim(s) <u>1-25</u> are subject to restriction a	nd/or election requirement.			
Application Papers				
9) The specification is objected to by the Ex	aminer.			
10) The drawing(s) filed on is/are: a)	☐ accepted or b)☐ objected to	by the Examiner.		
Applicant may not request that any objection	to the drawing(s) be held in abeya	nce. See 37 CFR 1.85(a).		
Replacement drawing sheet(s) including the	correction is required if the drawing	g(s) is objected to. See 37 CFR 1.121(d).		
11) The oath or declaration is objected to by	the Examiner. Note the attache	d Office Action or form PTO-152.		
Priority under 35 U.S.C. § 119				
12) Acknowledgment is made of a claim for f a) All b) Some * c) None of:	oreign priority under 35 U.S.C.	§ 119(a)-(d) or (f).		
1. Certified copies of the priority doc	uments have been received.			
2. Certified copies of the priority doc	uments have been received in A	Application No		
3. Copies of the certified copies of the	e priority documents have beer	received in this National Stage		
application from the International I				
* See the attached detailed Office action for	a list of the certified copies not	received.		
Attachment(s)				
1) Notice of References Cited (PTO-892)	4) Interview	Summary (PTO-413)		
2) Notice of Draftsperson's Patent Drawing Review (PTO-9 3) Information Disclosure Statement(s) (PTO-1449 or PTO	48) Paper No(	s)/Mail Datenformal Patent Application (PTO-152)		
Paper No(s)/Mail Date	6) Other:			

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## **DETAILED ACTION**

## **Election/Restrictions**

- 1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - Claims 1-15, drawn to a composition comprising a non-amphoteric glutathione derivative and a topically acceptable vehicle, classified in class 424, subclass 401.
  - II. Claims 16-25, drawn to a method of preventing or treating cosmeticcondition or a dermatological disorder, classified in class 514, subclass 2.

The inventions are distinct, each from the other because of the following reasons:

- 2. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process for using the product as claimed can be practiced with another materially different product such as vitamin A.
- 3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.
- 4. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance

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with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

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In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

5. Election of species should be required prior to a search on the merits in all applications containing both species claims and generic or Markush claims. (MPEP 808.01(a)).

This application contains claims directed to the following patentably distinct species of the claimed invention –

- a. N-acyl-glutathiones
- b. N-acyl-glutathione amides
- c. N-acyl-glutathione esters
- d. compounds of formula (I), which do not fall into any of the aforementioned groups

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These species are distinct because their structures and physicochemical properties differ. Accordingly, regardless of which group is elected, the Applicant is required to elect a single disclosed species from (a) – (d), even though this requirement is traversed. Applicant should include a chemical structure of the elected compound(s) if not already contained in the specification. Alternatively, the Applicant is invited to acknowledge these agents are obvious in view of one another. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

In addition, the Applicant is required to elect a single disclosed species of cosmetic, pharmaceutical or other topical agents recited in Claims 8, 9, 14, 15, 24 and 25. (For example, an election of retinoids of Claim 8, including retinal, 13-cis retinoic acid, retinoic acid, retinol, retinyl acetate and retinyl palmitate of Claim 9, would be proper response to the requirement). Furthermore, if Group II is elected, the Applicant is required to elect a single disclosed cosmetic condition or dermatological disorder of Claim 17.

To be complete, a response to the election of species requirement should include a proper election along with a listing of all claims readable thereon, including any claims subsequently added. MPEP 809.02(a).

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Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marina Lamm whose telephone number is (571) 272-0618. The examiner can normally be reached on Mon-Fri from 11am to 7pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Sreenivasan Padmanabhan, can be reached at (571) 272-0629.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marina Lamm

SREEN FAULTANABHAN SUPERVISORY PAVENT EXAMINER

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